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10/526,411	03/02/2005	Martin Klebsattel	13173-00009-US	9675

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CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/526,411	KLEBSATTEL ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *2-11;24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I and SEQ ID NO:1 in the reply filed on 09/20/2006 is acknowledged. The traversal is on the ground(s) that the reference cited by the Examiner does not anticipate the technical feature that is common to the restricted inventions. This is not found persuasive because not all claims specify the limitations that Applicant urges make the technical feature a contribution of the prior art. Several claims only limit the claimed promoter or method to having specificity for "nonreproductive floral tissue". The reference cited is a petal-specific promoter, which meets the limitation of "nonreproductive floral tissue", and the restriction requirement is therefore proper.

The requirement is still deemed proper and is therefore made FINAL.

Additionally, it is noted that with the election of SEQ ID NO:1, claims 2 and 15 are drawn to nonelected subject matter and are hereby withdrawn from examination. Claims 1, 14, and 16-23 are examined in the instant application.

Claim Objections

Claims 1, 14 and 16-23 are objected to because of the following informalities: Claims 1 and 14 recite nonelected sequences and therefore nonelected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-23 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. The claim broadly recites "a transgenic organism", which includes humans. Additionally, propagation material includes seeds which may not be transgenic.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, and 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "wherein the transgenic expression cassette comprises at least the following elements" wherein part (c) recites "optionally further genetic control elements". It is unclear how it is possible to "at least" comprise an element that is defined as being "optional(ly)". For the purposes of examination, element (c) is being examined as an optional element because of the word "optionally" at the beginning of the element. If Applicant intended the element to be required as suggested by the term "at least" the claim should be amended to reflect this requirement.

Claims 1 and 14 recite in parts a (ii and iii) functional equivalents or functional equivalent fragments with "essentially" the same promoter activity as a promoter of SEQ ID NO:1. Although the specification gives some guidance as to what is intended by the word "essentially", as illustrated in paragraph 43 of the specification, the metes and bounds of this categorization are not well-defined. It is not clear what tissues are being referred to or compared to with regard to tissue weight, and further does not define what is meant by "substantial". It is not clear what is considered to have "essentially" the same promoter activity as a promoter of SEQ ID NO:1, or "essentially in all nonreproductive floral tissues, but essentially not in the pollen and the ovaries." Furthermore, it is not clear whether "functional equivalent" is referring to promoter activity or the same **level** of promoter activity.

The method steps recited in claim 1 are not written in active form. The steps must be written in active form such as "introducing" and not "introduction".

Claim 16 recites in part (c) "a) and b) apply". It is unclear whether by "apply" it is intended that both a) and b) are present in the same expression cassette or not.

Claim 17 recites a nucleic acid sequence to be expressed that "makes possible" "the expression of a protein..." OR "the expression of a sense-RNA, anti-senseRNA....". It is unclear whether Applicant is claiming a single nucleic acid sequence that results in the subsequent expression of both a) and b), or the Applicant is claiming a nucleic acid that results in the subsequent expression of either a) or b), but not both.

Claims 16-19 recite "the nucleic acid to be expressed" which lacks antecedence. Claim 14 recites "nucleic acid sequences" rather than a single nucleic acid sequence.

Claims 20 and 21 recite "an expression cassette" of claim 14 rather than "the" expression cassette and therefore lack antecedence.

Claim 23 recites "selected from a group of agricultural crop plants". The claim does not properly list an actual group to be selected from, but merely recites a term that does not provide any limitation or metes and bounds to the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a transgenic expression cassette wherein the cassette comprises at least one promoter wherein the promoter is SEQ ID NO:1 or a functional equivalent with essentially the same promoter activity as a promoter of SEQ ID NO:1 or functional equivalent fragment of SEQ ID NO:1 with essentially the same promoter activity as a promoter of SEQ ID NO:1, at least one further nucleic acid sequence, and optionally further genetic control elements wherein at least one promoter and one

further nucleic acid sequence are functionally linked together as well as a transgenic organism and expression vector comprising said cassette.

In contrast, the specification, only provides guidance for targeted transgenic "expression". The specification does not provide guidance for an expression cassette with any "further" nucleic acid as recited in claim 1 and 14. Therefore Applicant is not enabled for a "further" nucleic acid without the limitation of a protein-encoding sequence.

Furthermore, claim 17 is not enabled for second expression of a) or b) based on the expression in line 2 of the claim. Applicant has not disclosed a sequence that when expressed transgenically "makes possible" the expression of a protein encoded by said nucleic acid OR the expression of a sense-RNA, anti-sense RNA or double-stranded RNA encoded by said nucleic acid sequence. No such self-regulatory feedback nucleic acids have been disclosed in the specification, and Applicant is therefore not enabled for such sequences.

Given the state of the art, and the lack of guidance as discussed above, it would require undue experimentation by one of skill in the art to identify and evaluate nucleic acids for their ability to self regulate and make possible their own expression as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 16-17, and 20-23 rejected under 35 U.S.C. 102(b) as being anticipated by Axelos et al (1989 Mol Gen Genet 219:106-112) and (Genbank ATU63815).

The claims are drawn to a transgenic expression cassette wherein the cassette comprises at least one promoter wherein the promoter is SEQ ID NO:1 or a functional equivalent with essentially the same promoter activity as a promoter of SEQ ID NO:1 or functional equivalent fragment of SEQ ID NO:1 with essentially the same promoter activity as a promoter of SEQ ID NO:1, at least one further nucleic acid sequence, and optionally further genetic control elements wherein at least one promoter and one further nucleic acid sequence are functionally linked together as well as a transgenic organism and expression vector comprising said cassette.

Axelos et al teach functional equivalents of SEQ ID NO:1 as well as SEQ ID NO:1 (see GenBank ATU63815), as well as an expression vector comprising said sequences (see Figure 5 and page 110 2nd paragraph, in particular) and the transformation of Arabidopsis with said expression vector. The further heterologous nucleic acid is the GUS reporter gene, and as discussed above, the further genetic control elements are claimed as being optional.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 14, and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al (US Patent 6320102) in view of Axelos et al (1989 Mol Gen Genet 219:106-112) and (GenBank ATU63815), in view of Roessler et al (1993 The Journal of Biochemistry 268:19254-19259) and further, in view of Koes et al (1986 Nucleic Acids Research 14:5229-5239).

The claims are drawn to a method for the targeted transgenic expression of nucleic acid sequences in nonreproductive floral tissues of plants comprising the introduction of a transgenic expression cassette into plant cells wherein the cassette comprises at least one promoter wherein the promoter is SEQ ID NO:1 or a functional equivalent with essentially the same promoter activity as a promoter of SEQ ID NO:1 or functional equivalent fragment of SEQ ID NO:1 with essentially the same promoter activity as a promoter of SEQ ID NO:1, at least one further nucleic acid sequence, and optionally further genetic control elements wherein at least one promoter and one further nucleic acid sequence are functionally linked together, selection of transgenic cells comprising the expression cassette, and regeneration of complete plants from said transgenic cells. The claims are also drawn to the transgenic expression cassette described above wherein the expression of a protein is made possible wherein the protein is selected from list of known proteins, a transgenic expression vector comprising the expression cassette and a transgenic organism comprising said vector.

Harada et al teach a method for targeting expression of a polynucleotide in a seed comprising introducing into a plant a LEC1 promoter operably linked to a heterologous polynucleotide sequence wherein the polynucleotide sequence encodes a polypeptide (see claims 1 and 2, for example), the selection of cells comprising the expression cassette and the regeneration of whole plants from the transgenic cells (see Column 21, lines 32-47, for example), as well as the expression cassette and expression vector (see Column 15, lines 59-67, and Column 16, lines 36-61, for example).

Harada et al do not teach a method for targeting expression of a polynucleotide to nonreproductive floral tissues of plants with an expression cassette comprising a promoter wherein the promoter is SEQ ID NO:1, however, Harada et al do teach the use of tissue specific promoters including petal and sepal specific promoters (see Column 18, lines 45-54, and Column 19, lines 3-18, for example) which would inherently be functional equivalents of functional equivalent fragments of SEQ ID NO:1, given the broad definition of functional equivalents by Applicant as any mutated, deleted, or hybridizing nucleic acid sequence under standard conditions (including standard low stringency hybridization). Furthermore, Harada et al suggest the use of such tissue specific promoters in the statement "Alternatively, the plant promoter may direct expression of the polynucleotide of the invention in a specific tissue" (see column 18 lines 33-36) followed by the above mentioned example of petal and sepal specific promoters. Additionally, Harada et al suggest the expression of other structural or

regulatory genes with LEC1 nucleic acids (see Column 21, lines 65-67 and Column 22 lines 1-4, for example).

Axelos et al teach functional equivalents of SEQ ID NO:1 as well as SEQ ID NO:1 (see GenBank ATU63815), as well as an expression vector comprising said sequences (see Figure 5 and page 110 2nd paragraph, in particular).

Given the state of the art, the disclosures by Harada et al, Axelos et al, Koes et al, and Roessler et al, it would have been obvious to one of ordinary skill in the art to modify the method taught by Harada et al, by using the promoter taught by Axelos et al as suggest by Harada et al. The heterologous genes listed in the claims are well-known genes that are taught in the art and are a matter of design choice. By way of example, the Chalcone synthase gene as metioned in claim 19 "GenBank Acc.-No M20308" is taught by Koes et al (see abstract and Figure 3), and the acetyl-coA carboxylase mentioned in claim 18 is taught by Roessler et al (see abstract and figure 2), therefore it would have also been obvious to one of ordinary skill in the art to modify the method taught by Harada et al by using the promoter taught by Axelos with the genes taught by Roessler et al and Koes et al, as suggested by Harada et al.

No Claims are allowed.

No Claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

Phuong T Bui 11/27/06

PHUONG T. BUI
PRIMARY EXAMINER